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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,773	11/28/2001	Yoshinobu Hanyu	P21651	9572

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/994,773	Hanyu
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *3/4/02 and 11/28/01*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/810,483.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-24 are rejected over the recitation of the phrase, "organic binder". It is not clear what binder molecule is claimed in this invention. Is the binder molecule itself organic in chemical nature or the binder molecule binds with organic molecules or both the molecules are organic in nature? The metes and bound of the claim is vague and indefinite.

Claims 10 and 22 are rejected over the improper Markush species, "superoxide". It is also not clear if two new physiologically active peptides named "superoxide" and "dismutase" are claimed or whether it should be read as "superoxide dismutase". Proper correction is suggested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 8, 10-17, 20, 23, and 24 are rejected under 35 U.S.C. 102 (b) as being anticipated by Samaritani (PCT International Publication NO: WO 95/35116) (December 28, 1995).

Samaritani teaches a method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid at least one compound selected from mannitol (Abstract, and Table 1, in this case HGH 1-3, and HGH 5-7).

Samaritani teaches a method for stabilization of a physiologically active peptide, wherein the powder is made up of particles comprising a physiologically active peptide and mannitol at a weight proportion of 1:1 to 1:50 (Claims 1, 2 and 5 and Table 1 and Page 3, lines 3-5 and Page 5, lines 1-6). Samaritani teaches that the ratio of physiologically active peptide and mannitol is precisely 1:6.4 (Table 1).

Samaritani teaches a method for preparing a powder containing a physiologically active peptide, wherein the particles further comprise a water-soluble, nonionic, organic binder in an amount of 6 parts (precisely 5.93 parts) by weight (Claim 5 and Table 1).

Samaritani teaches a method for preparing powder containing a physiologically active peptide, for which drying of the aqueous liquid was performed by lyophilization. (Page 5, lines 7-14 and Claim 2).

Samaritani teaches a method for preparing powder containing a physiologically active peptide, wherein the physiologically active peptide is human growth hormone (Abstract, and Claims 1, 2 and 5 and Table 1 and Page 3, lines 3-9).

5. Claims 1, 7, 13, and 19 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bjorn et al. (PCT International Publication NO: WO 97/39768) (October 30, 1997).

Bjorn et al teaches a method for stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide, wherein the method comprises adding to the aqueous liquid at least one compound selected from a nonionic surfactant polysorbate or poloxamer (Abstract and Page 11, line 30 to page 13, line 25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 9, 21, and 22 are rejected under 35 U.S.C. 103 (a) over Samaritani (PCT International Publication NO: WO 95/35116) (December 28, 1995) in view of Shigehara et al. (U.S. Patent 5,763,439) (June 9, 1998).

Samaritani teaches the powder composition of claims 1-6, 8, 10-17, 20, 23, and 24 as described above.

Samaritani does not teach the composition, wherein the average size of the particles is 1-10 micrometer.

Shigehara et al teach the composition, wherein the average size of the particles is 1-10 micrometer (Column 7, line 66 to column 8, line 1).

Samaritani does not teach a vasculogenesis factor composition containing a physiologically active peptide.

Shigehara et al teach a vasculogenesis factor composition containing a physiologically active peptide. (Column 7, line 59 to Column 8, line 5).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the inhalant composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Shigehara et al into the powder composition of Samaritani, since Shigehara et al. state, "a drug formulation suitable for topical or per rectal administration may, for example, be an inhalant, an

ointment or a suppository. The inhalant may be administered to the respiratory airway in the form of fine powder for inhalation. Such an inhalant may be used, if necessary, in combination with other antiashematic agent or bronchodilator, corticosteroid or ACTH (Adrenocorticotropic hormone) (Column 7, line 59 to Column 8, line 5)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the inhalant composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Shigehara et al into the powder composition of Samaritani in order to improve the inhalant drug formulation. An ordinary practitioner would have been motivated to combine and substitute the inhalant composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Shigehara et al into the powder composition of Samaritani in order to achieve the express advantages noted by Shigehara et al., of an inhalant drug formulation suitable for topical or per rectal administration that may be administered to the respiratory airway in the form of fine powder for inhalation and which may be used, if necessary, in combination with other antiashematic agent or bronchodilator, corticosteroid or ACTH.

8. Claim 18 is rejected under 35 U.S.C. 103 (a) over Samaritani (PCT International Publication NO: WO 95/35116) (December 28, 1995) in view of Morita et al. (U.S. Patent 6,156,343) (December 5, 2000).

Samaritani teaches the powder composition of claims 1-6, 8, 10-17, 20, 23, and 24 as described above.

Samaritani does not teach the method wherein the water-soluble, nonionic cellulose derivative is selected from hydroxypropylmethylcellulose.

Morita et al teach the method wherein the water-soluble, nonionic cellulose derivative is selected from hydroxypropylmethylcellulose (Claim 8, Tables 1 and 4, and Column 8, lines 10-18).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method wherein the water-soluble, nonionic cellulose derivative is selected from hydroxypropylmethylcellulose. of Morita et al into the powder composition of Samaritani, since Morita et al. state, "In addition to that, when a drug is instable to light, to stabilize the drug, for example, hydroxypropylmethylcellulose is dissolved or dispersed in water, and/or in organic solvent, and the resulting solution may be sprayed on the controlled release preparation of this invention and the preparation may be dried to prepare the label coated with the membrane for protecting from light on the tablet (Column 8, lines 10-18)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method wherein the water-soluble, nonionic cellulose derivative is selected from hydroxypropylmethylcellulose. of Morita et al into the powder composition of Samaritani in order to improve the drug formulation. An ordinary practitioner would have been motivated to combine and substitute the method wherein the water-soluble, nonionic cellulose derivative is selected from hydroxypropylmethylcellulose. of Morita et al into the powder composition of Samaritani in order

to achieve the express advantages noted by Morita et al., of hydroxypropylmethylcellulose which is used to stabilize the drug when a drug is instable to light.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, who can be reached on (703) 308-1119. The Group analyst Chantae Dessau can be reached at 703-605-1237. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun K. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

February 11, 2003